

DETAILED ACTION

Election/Restrictions

NOTE: Claims 5 and 7 provide for the use of a compound of formula (I) as defined in either of claims 1 or 2, but, since the claims do not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced. Furthermore, the claimed invention outlined by claim 5 and 7 is directed to non-statutory subject matter. The claimed invention does not fall within at least one of the four categories of patent eligible subject matter recited in 35 U.S.C. 101 (process, machine, manufacture, or composition of matter). Accordingly, claims 5 and 7 have not been placed into groups for the purposes of this restriction requirement.

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. The inventions listed as Groups I-IV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The common technical feature linking the claims compounds of formula (I) for the treatment or prophylaxis of androgen receptor-mediated conditions. This element cannot be a special technical feature under PCT Rule 13.2 because the element is shown in the

prior art. Malm et al. (WO 01/36365) teaches several compounds which fall within instant formula (I) (pages 5-6 and examples 1-121) as well as their use for the treatment of diseases dependent on the expression of T3 regulated gene or associated with metabolic dysfunctions, which include hirsutism and acne which are known androgen mediated diseases (claims 12-16). As a result, no special technical features exist among the different groups because the inventions in Groups I-IV fail to make a contribution over the prior art. In conclusion, Groups I-IV are not so linked by the same or a corresponding special technical feature as to form a single general inventive concept, and therefore, restriction for examination purposes as indicated is proper.

Because the species encompassed by Applicants' genus of formula (I) are far too varied and abundant to set forth individually, the Examiner cannot reasonably enumerate the incredible number of compounds encompassed by the claims. Accordingly, in accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 1-3, 6 and 9-11, drawn to a single species of a compound of formula (I) and composition comprising the same.

Group II, claim 4, drawn to a method of the treatment or prophylaxis of a condition in a mammal mediated by an androgen receptor, which comprises administering to the mammal a therapeutically effective amount of a single species of a compound of formula (I).

Group III, claim 8, drawn to a method of discovering a ligand of the androgen receptor which comprises the use of a single species of compound (I) or (Ia) or a single species of compound (I) or (Ia) in labeled form.

Group IV, claim 12, drawn to a method for preparing a single species of compound of formula (Ib) or (Ic).

The inventions listed as Groups I-IV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features as discussed infra.

Due to the complicated nature of the restriction, the restriction requirement is being made via written correspondence in lieu of a telephone interview.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are

subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kortney Klinkel whose telephone number is (571)270-5239. The examiner can normally be reached on Monday-Friday 8am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached at (571)272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

KLK

/Sharmila Gollamudi Landau/

Supervisory Patent Examiner, Art Unit 1611